

REMARKS

Claims 1-26 are pending in the present application. By virtue of this response, claims 2, 3, 5, 6, 23, 24, and 26 have been canceled. Claims 1 and 25 have been amended. No new claims have been added. Therefore, after entry of the above amendments, claims 1, 4, 7-22, and 25 will be under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any claimed subject matter previously presented.

Rejection of claims under 35 U.S.C. §102(b)

Claims 1-7, 13, 14, 20, 21 and 23-26 stand rejected under 35 U.S.C §102(b) as anticipated by U.S. Patent Nos. 6,060,085 or 5,863,560, both to Osborne ('085 and '560). In support of this rejection the Office Action states that “[b]oth references teach dapsone in a topical composition and for the same purpose i.e., treatment of acne. Accordingly, the ability to treat inflammatory and non-inflammatory acne is inherent to the composition of both references” (emphasis added). Applicant disagrees.

Claim 1, from which claims 2-22 depend, has been amended to recite a method for “reducing a number of non-inflammatory acne lesions” (emphasis added). The '085 and the '560 patents fail to teach or disclose such a method. To be sure, not all acne is the same. Some acne results in inflammation and inflammatory lesions, while other acne does not. In this regard, Applicant notes that the Osborne patents fail to disclose even a single instance of treating non-inflammatory acne lesions with a dermatological composition, let alone a treatment regime that specifically calls for reducing a number of non-inflammatory acne lesions.

In addition, contrary to the Office Action assertion, the ability to treat non-inflammatory acne is not inherent in the compositions of Osborne. The mere fact that a certain result or characteristic may occur or be present in a cited reference is not sufficient to establish the inherency of that result or characteristic. *See* MPEP §2112 (citing *In re Rijckaert*, 9. F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)). Indeed, in order to rely on inherency as a basis of rejection, the Examiner must provide a basis in fact and, or in the alternative, technical reasoning to

reasonably support a conclusion that an allegedly inherent characteristic “necessarily flows” from the teachings of the cited art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Applicant notes that the Examiner has set forth no such basis or reasoning here.

In addition to providing an adequate basis for relying on inherency, evidence relied upon by the Examiner, “must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ3d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added). The Examiner has failed to provide Applicant with any such evidence. Such evidence would be quite difficult to furnish, since persons of ordinary skill in the art would not have recognized that a dermatologic composition comprising dapsone would be effective in the treatment of non-inflammatory acne (especially since dapsone is an anti-inflammatory agent). Applicant notes that a new use for a known composition, based on unknown properties, is patentable. See MPEP §2112 citing *In re Hack*, 245 F. 2d 246, 248 114 USPQ 161, 163 (CCPA 1957). Accordingly, Applicant submits that the rejections under 35 U.S.C. §102 are improper.

Claims 23, 24, and 26 have been canceled rendering their rejection under 35 U.S.C. §102 moot. Claim 25 recites a method for treating “non-inflammatory acne.” A discussion of the failure of the cited references to teach or disclose a method for treating “non-inflammatory acne” was discussed just above, and that discussion applies here as well. Accordingly, for at least the same reasons presented above, the rejection of claim 25 under 35 U.S.C. §102 is improper.

Applicant respectfully requests that the rejections under 35 U.S.C. §102 be withdrawn.

Rejection of claims under 35 U.S.C. §103(a)

Claims 1-26 stand rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 6,200,964 to Singleton et al. ('964) in view of the Osborne patents ('085 or '560). In support of this rejection the Office Action states that it “would have been obvious to one of an ordinary skill in the art at the time of the instant invention to use dapsone in the composition of '964 as an additional anti-acne agent because Osborne teaches dapsone as an effective anti-acne agent and using dapsone

in a dissolved and a microparticulate form in the same composition enables immediate treatment of inflammation as well as prevention of inflammatory lesions” (emphasis added). Applicant disagrees with this rejection.

In order to set forth a *prima facie* case of obviousness, the references must teach or suggest all the claim limitations, there must be some suggestion or motivation to modify the references or combine their teachings, and there must be a reasonable expectation of success, *see* MPEP §2143. Applicant submits that the Office Action fails to set forth even a *prima facie* case of obviousness. To be sure, at a minimum, the references fail to teach or suggest each and every claim limitation.

The ‘085 and ‘560 patents were discussed in detail above, where it was submitted that they failed to expressly or inherently teach or disclose methods for treating non-inflammatory acne, or methods for reducing the number of non-inflammatory acne lesions. The above quoted language of the Office Action supports this conclusion by making reference only to the treatment of inflammation or inflammatory lesions. In addition, by the Office Action’s own admission, the ‘964 patent fails to cure this deficiency. (*See* Office Action, page 3, paragraph 3, stating that the “‘964 fails to explicitly teach dapsone for treating acne”). Therefore, for at least the reason that the combination of references fails to teach or suggest each and every claim limitation, the rejections under 35 U.S.C. §103(a) are improper.

Accordingly, Applicant respectfully requests that the rejections under 35 U.S.C. §103(a) be withdrawn.

Rejection of claims under 35 U.S.C. §112, second paragraph

Claims 1-26 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Specifically, the Office Action states that the claims are indefinite because it is, “vague and unclear from the claims if the composition is applied to even normal skin” or “applied to acne lesion and/or non-inflammatory acne lesion.” Applicant has amended claim 1, from which claims 1-22 depend, to recite that the dermatological composition is applied to non-inflammatory acne lesions. Similarly, claim 25 has been amended to recite that the dermatological composition is topically

applied to the non-inflammatory acne. Claims 23, 24, and 26 have been canceled rendering their rejection moot.

Applicant submits that all claims comply with 35 U.S.C. §112, and respectfully requests that the rejections under this section be withdrawn.

Rejection of claims under 35 U.S.C. §112, first paragraph

Claim 24 stands rejected under 35 U.S.C. §112, first paragraph, for failure of enablement.

Claim 24 has been canceled, rendering this rejection moot.

Accordingly, Applicant respectfully requests withdrawal of this rejection.

CONCLUSION

Applicant has, by way of the amendments and remarks presented herein, made a sincere effort to overcome the rejections and to address all issues raised in the outstanding Office Action. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **03-1952** referencing docket no. 359872001400. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: December 8, 2003 2003

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